

# Minimally Invasive Glaucoma Surgery: iStent and Preserflo in the Treatment of Primary Open-Angle Glaucoma. A Review

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Submitted to the editorial board: June 18, 2025

Accepted for publication: July 19, 2025

Available on-line: October 10, 2025

*The authors of the study declare that no conflict of interests exists in the compilation, theme and subsequent publication of this professional communication, and that it is not supported by any pharmaceuticals company. The study has not been submitted to any other journal or printed elsewhere, with the exception of congress abstracts and recommended procedures.*

## SUMMARY

Glaucoma is a chronic, progressive and irreversible neuropathy of the optic nerve, characterized by morphological changes in the optic nerve papilla and defects in the visual field. Although the precise pathogenesis is not fully understood, the current concept of glaucoma development incorporates the deformation of the lamina cribrosa caused by elevated intraocular pressure, leading to axonal damage, subsequent apoptosis of retinal ganglion cells and loss of the nerve fiber layer. This review article discusses the current possibilities of using minimally invasive glaucoma surgery, specifically focusing on the micro-invasive implants iStent and Preserflo, their efficacy and safety in the surgical treatment of primary open-angle glaucoma.

**Key words:** primary open-angle glaucoma, minimally invasive glaucoma surgery, iStent, Preserflo Microshunt

*Čes. a slov. Oftal., 82, 2026, No. 2, p. 67–71*

## PRIMARY OPEN-ANGLE GLAUCOMA (POAG)

Glaucoma ranks among the main causes of irreversible loss of sight worldwide. It is a chronic, progressive and irreversible neuropathy of the optic nerve (ON), characterized by morphological changes in the optic nerve papilla and defects in the visual field. Although the precise pathogenesis is not fully understood, the current concept of glaucoma development incorporates the deformation of the lamina cribrosa caused by elevated intraocular pressure (IOP), leading to axonal damage, with subsequent apoptosis of the retinal ganglion cells and loss of the nerve fiber layer [1–4]. We indicate surgical treatment if conservative treatment has failed to attain the target IOP values, upon progression of the ocular finding to the patient's ON papilla, upon progression of defects in the visual field or progressive loss of nerve fibers verified by examination by optical coherence tomography, as well as in the case of intolerance of local therapy or non-compliance on the part of the patient [5]. Trabeculectomy, ab-externo filtration surgery, still remains the gold standard in glaucoma surgery, predominantly for patients with advanced or rapidly progressing pathology. However, this may be associated with a series of perioperative and postoperative complications – hypotonia, infection, suprachoroidal hemorrhage, progression of cataract

etc. [6,7]. Implants of minimally invasive glaucoma surgery (MIGS) have been developed as safer and less traumatic surgical interventions for patients with mild to medium-severe glaucoma, or for those who are intolerant to standard pharmacological therapy. In comparison with traditional glaucoma operations, MIGS offers a better safety profile and faster patient convalescence after surgery. In general MIGS implants are indicated for patients with mild or medium-severe glaucoma, since the resulting effect on reducing intraocular pressure may be less pronounced than in the case of traditional glaucoma operations [8–10]. It is necessary to take this fact into account when deciding on which surgical procedure to choose for the given patient, since it potentially limits the effectiveness of MIGS implants in the case of advanced glaucoma or in patients with a low target IOP. Furthermore, whereas MIGS implants have demonstrated promising results in the short-term and medium-term perspective, the long-term results and comparative effectiveness among the various MIGS technique remain the subject of investigation [11].

## iStent

Minimally invasive glaucoma surgery has brought about an important advance in reducing intraocular pre-

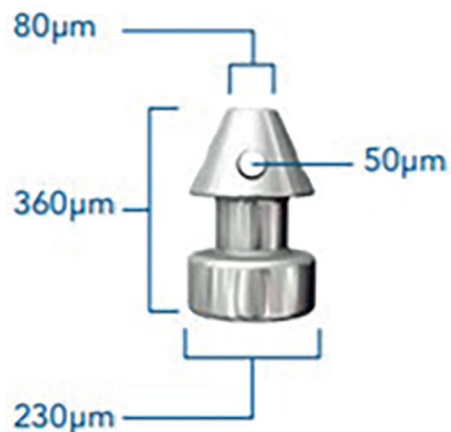
ssure in patients with mild to medium-severe primary open-angle glaucoma. At the head of this innovation is the range of iStent implants (Glaukos Corporation, Laguna Hills, CA, USA), which have been progressively developed in four generations.

**1<sup>st</sup> generation – iStent inject®**

The first iStent model was approved by the Food and Drug Administration (FDA) in 2012, and became a pioneer in the MIGS category. It was produced from titanium (Ti6A14V ELI) in the shape of a letter “L”, with a length of 1 mm and a diameter of 0.3 mm, and coated with heparin (Duraflon, Edwards LifeSciences, Irvine, CA). It was implanted in the Schlemm’s canal with the aid of a minimally invasive inserter (Figure 1). One stent was always implanted. The clinical data according to Samuelson et al. (2011) demonstrated a reduction of average IOP from 21.5 mmHg to 17 mmHg after 12 months, in which 72% of patients attained values of ≤ 21 mmHg without the need for medication. A reduction of glaucoma drops was recorded in 15% of patients, in comparison with 1% in the control group, where only cataract surgery was performed [12].

**2<sup>nd</sup> generation – iStent inject®**

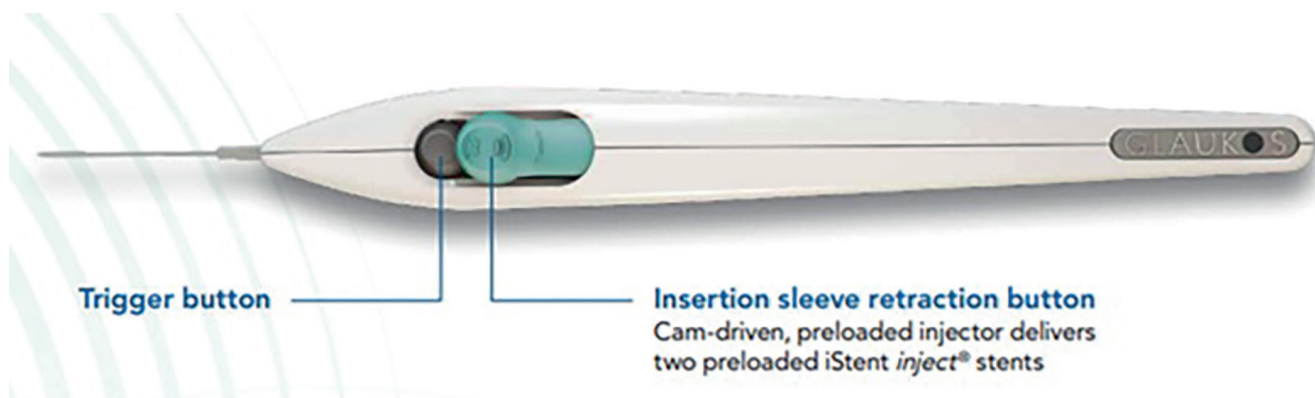
The second generation was launched onto the market in 2018. Each injector contains two titanium stents applied into the Schlemm’s canal. The model of the second generation differs from the first generation in its improved drainage of chamber fluid, thanks to four lateral offtakes with a diameter of 50 μm (Figure 2). During the course of a two-year observation period, Samuelson et al. (2019) investigated the safety and efficacy of a combination of implantation with cataract surgery in patients with mild or medium-severe POAG. In comparison with cataract surgery alone they recorded a greater reduction of IOP in the combined procedure [13]. This multicentric study incorporated 505 eyes with mild or medium-severe POAG, which also required cataract surgery. Preoperative treated IOP was ≤ 24 mmHg and



**Figure 2.** iStent inject®. Source: [www.glaukos.com](http://www.glaukos.com)

untreated IOP was within a range from 21 to 36 mmHg. Following uncomplicated cataract surgery the eyes were perioperatively randomized either for the insertion of an iStent Inject (treated group, n = 387), or remained without a stent (control group, n = 118). The subsequent observation then continued for two years. Among the respondents, 84% of treated eyes and 67% of control eyes received no ocular antihypertensive agents after 23 months. By 24 months, daily IOP without medication of ≤ 18 mmHg was attained in 63.2% of the treated eyes and 50.0% of the control eyes [13].

Hengerer et al. (2022) as part of a five-year prospective longitudinal study also compared the efficacy and safety profile of implantation of a 2nd generation iStent separately or in combination with cataract surgery. The study numbered 125 eyes with POAG, which were divided into two groups. In the subgroup with a combination of implantation and phacoemulsification there was a 39% reduction of IOP (from 22.6 mmHg to 13.8 mmHg, p = 0.001) and a 69% re-



**Figure 1.** iStent® injector. Source: [www.glaukos.com](http://www.glaukos.com)

duction of medications (from 2.52 to 0.78,  $p = 0.001$ ), in the subgroup with implantation alone there was a 42% reduction of IOP (25.3 mmHg to 14.6 mmHg,  $p = 0.001$ ) and a 75% reduction of medications (2.98 to 0.74,  $p=0.001$ ). More than 83% of eyes achieved a reduction of IOP by  $\geq 20\%$ , and in more than 99% of eyes IOP remained the same or lower than before surgery, with 46% of patients without medication. Over the course of five years no postoperative complications ensued, no filtration operation was required and glaucoma was stabilized [14].

### 3<sup>rd</sup> generation – iStent inject® W

In 2020 the modified model iStent inject W was introduced, with a broader base of the stent (360  $\mu\text{m}$  in comparison with 230  $\mu\text{m}$  of the second generation) and an improved injector, which increases surgical precision and reduces the risk of incorrect implantation (Figure 3). Here also, two stents are implanted within the context of phacoemulsification cataract surgery. Deneri et al. (2023) from the University Eye Clinic in Münster, Germany, published a retrospective study which compared the short-term and medium-term postoperative results of implantation of an iStent Inject® and iStent Inject® W in combination with cataract surgery in patients with POAG. A total of 67 eyes were included in the study. Cataract surgery was performed on all eyes, an iStent Inject was implanted in 35 eyes and an iStent Inject W in 32 eyes. The observation period was 6 months. The main target parameter for success was a reduction of the baseline value of IOP at the end of the observation period. The secondary observed parameters included reduction of IOP on the first day after surgery, changes on the perimeter, changes

in the nerve fiber layer, reduction of antiglaucoma pharmacotherapy and the presence of postoperative complications. Both groups recorded a statistically significant reduction of IOP. The group with iStent Inject W recorded a statistically significant reduction on the first day after surgery and also after six months, whereas in the group in which an iStent Inject had been implanted a statistically significant reduction of IOP was recorded only on the first day after surgery [15]. The study also demonstrated a statistically significant reduction of antiglaucoma pharmacotherapy. At the end of the observation period there was a greater reduction of antiglaucoma pharmacotherapy in the group with implantation of an iStent Inject than in the group with an iStent Inject W [15]. There may be multiple reasons for this: the different approach in medication with the implant with better effectiveness, the conservative approach of doctors in the case of the newer model and limiting factors of the study itself (retrospective design, small sample, short observation period). No statistically significant difference was demonstrated in the incidence of postoperative complications in both the observed groups of patients [15]. The authors of the study stated that the larger base of the iStent Inject W may lead to better placing of the stent and thereby to more effective reduction of IOP. More extensive and longer observation would be required for definitive conclusions concerning the long-term efficacy and safety of both devices [15].

### 4<sup>th</sup> generation – iStent infinite (G4)

The latest model, approved in August 2022, has brought about a fundamental advance. It consists in an implantation of a total of three stents into the Schlemm's

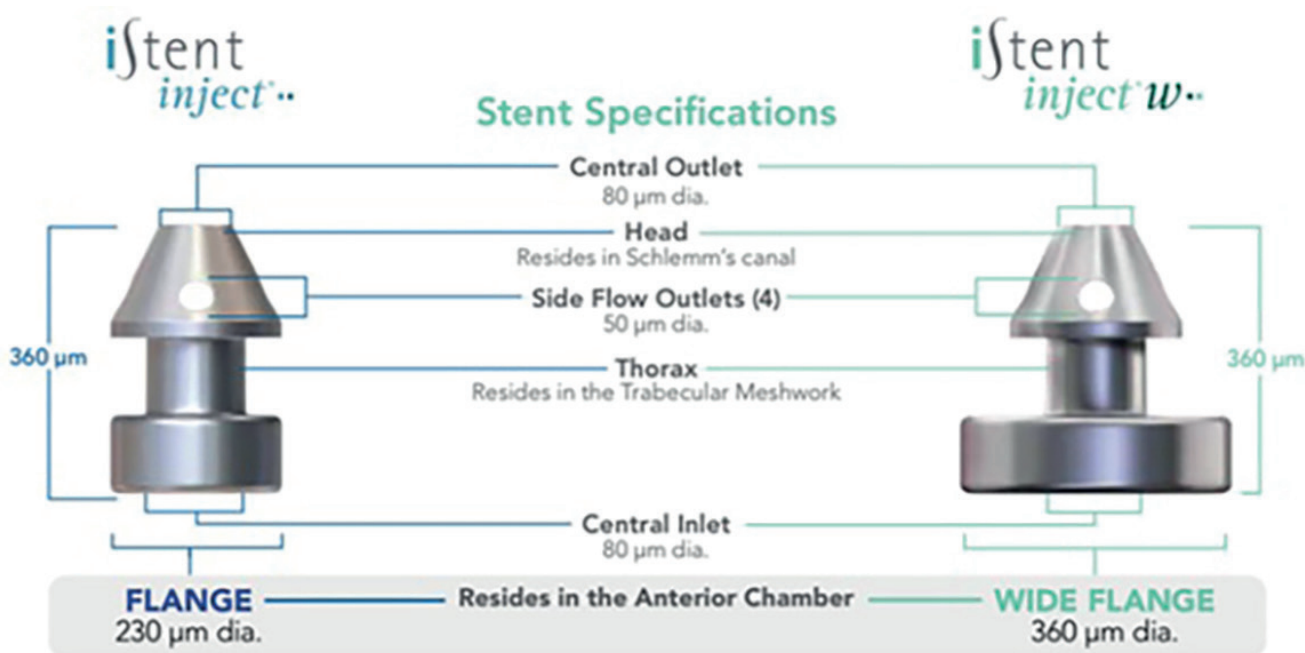


Figure 3. Comparison between the second and third model of iStent. Source: [www.glaukos.com](http://www.glaukos.com)

canal independently of the current execution of phacoe-mulsification of the intraocular lens.

The results of the registration FDA study, incorporating 72 patients and 72 eyes, demonstrated that an average reduction of IOP by  $\geq 20\%$  was achieved in 76% of patients in comparison with the baseline values, while maintaining or reducing the number of used medications. The safety profile was excellent, with a minimum of complications and without the need for reoperation [16].

### PRESERFLO™ MicroShunt

PRESERFLO™ MicroShunt (Santen Pharmaceutical Co., Ltd.,) is a small, flexible tube produced from biocompatible material known as poly(styrene-block-isobutylene-block-styrene), or SIBS, which is designed in order to minimize inflammation, scarring and fibrosis. It is a tube with a length of 8.5 mm, which has a lumen with a diameter of 70  $\mu\text{m}$  and an external diameter of 350  $\mu\text{m}$  (Figure 4). It is implanted using the “ab-externo” technique, i.e. one end is inserted into the anterior chamber of the eye, while the other end is threaded beneath the conjunctiva into the sub-Tenon space, where a filtration bleb is created. The intraocular implant can be inserted separately, or its implantation can be combined with cataract surgery [17,18]. Fili et al. (2022) in a prospective observational study on 30 eyes compared the efficacy and safety of implantation of Preserflo both separately and in combination with cataract surgery. The patients were divided equally into two groups. The baseline IOP value in the group with separate implantation was  $23.5 \pm 9.0$  mmHg, in the other group the IOP value was  $23.4 \pm 8.7$  mmHg. After twelve months of observation the average IOP value in the first group was  $11.6 \pm 1.6$  mmHg, in the second group  $13.8 \pm 3.6$  mmHg. There was no statistically significant difference in the absolute reduction of IOP during the 12 months after surgery between the two groups ( $p = 0.056$ ) [18]. According to other published studies, Preserflo represents an effective and safe method in the treatment of POAG, leading to a reduction of IOP and the number of antiglaucoma medications [19–22].



Figure 4. Preserflo™ implant. Source: www.santen.com

## CONCLUSION

The current data support the use of both micro-invasive implants – iStent and Preserflo MicroShunt – as effective and safe options for the surgical treatment of glaucoma, especially in patients with mild to medium-severe advanced form of the disease. The choice between these implants should be based on the patient’s individual requirements, the degree of glaucoma affliction and consideration of the risks and benefits.

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